K091241

510(k) Summary

MAR 18 2010

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
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Contact Person: Kathie J. Goodwin

Date Prepared: June 10, 2009

Device Name

Proprietary names: Tina-Quant Ceruloplasmin

Common names: Ceruloplasmin assay

Classification names: Ceruloplasmin Immunological Test System

Product codes: CHN

Device Description

The Tina-quant Ceruloplasmin assay employs an immunoturbidimetric test in which anti-ceruloplasmin antibodies react with antigen in the sample to form antigen/antibody complexes which, following agglutination can be determined turbidimetrically.

Intended use

Immunoturbidimetric assay for the quantitative in vitro determination of ceruloplasmin in human serum and plasma on Roche automated clinical chemistry analyzers.

Indications for Use

Measurements obtained by this device aid in the diagnosis of copper metabolism disorders.

Substantial equivalence

The Tina-quant Ceruloplasmin assay is substantially equivalent to the Roche Ceruloplasmin assay on the cobas c501 analyzer. The cobas c501 Ceruloplasmin assay was cleared under K062114.

510(k) Summary, Continued

Substantial equivalence – comparison

Feature	Tina-quant Ceruloplasmin Assay	Predicate Device: cobas c501 Ceruloplasmin Assay (K062114)
Intended Use	Immunoturbidimetric assay for the quantitative in vitro determination of ceruloplasmin in human serum and plasma on **Roche automated clinical chemistry analyzers.**	Immunoturbidimetric assay for the quantitative in vitro determination of ceruloplasmin in human serum and plasma on **Roche/Hitachi cobas c systems.**
Indication for Use	Measurements obtained by this device aid in the diagnosis of copper metabolism disorders.	Same
Assay Protocol	Immunoturbidimetric	Same
Sample Type	Serum and Li-heparin Plasma	Same
Labeled Instrument Platform	Roche/Hitachi analyzers	Roche Hitachi cobas c systems
Calibrator	C.f.a.s. PAC	Same
Calibration frequency	Full calibration is recommended after reagent lot change and as required following quality control procedures.	Same
Controls	Commercially available control	Same
Traceability	Standardized against the reference preparation CRM 470 (RPPHS – Reference Preparation for Proteins in Human Serum)	Same
Reagent Stability	3 days at 2-8 Deg. C 4 weeks at (-15)-(-25) Deg. C	Same
Measuring Range	3-140 mg/dL	Same

Precision	Repeatability (Within-run) • Control Low: SD 0.4 mg/dL; CV 1.5% • Control High: SD 0.9 mg/dL; CV 0.9% • Serum Low: SD 1.2 mg/dL, CV 1.2% • Serum Medium: SD 0.5 mg/dL, CV 0.8% • Serum High: SD 0.9 mg/dL, CV 0.8% Intermediate Precision (Total) • Control Low: SD 0.4 mg/dL; CV 1.6% • Control High: SD 0.7 mg/dL; CV 1.1% • Serum Low: SD 0.4 mg/dL, CV 1.6% • Serum Medium: SD 0.7 mg/dL, CV 1.0% • Serum High: SD 1.1 mg/dL, CV 0.9%	Within-run • Precinorm Protein: SD 0.2 mg/dL; CV 0.6% • Precipath Protein: SD 0.2 mg/dL; CV 0.6% • Human Serum 1: 0.3 mg/dL, CV 1.5% • Human serum 2: 0.3 mg/dL, CV 0.8% Total • Precinorm Protein: SD 0.4, CV 1.4% • Precipath Protein: SD 0.4, CV 1.0% • Human Serum 3: SD 0.5, CV 2.6% • Human Serum 4: SD 0.7, CV 1.5%
Analytical Sensitivity	Limit of Blank (LoB) $\leq$2 mg/dL Limit of Detection (LoD) $\leq$3 mg/dL	Lower Detection Limit = 3 mg/dL
Analytical Specificity	No interference was found at common therapeutic concentrations using common drug panels.	Same

Interferences	*Criterion: Recovery within ± 10% of initial value.* Icterus: no significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL) Hemolysis: No significant interference up to an H index of 350 (approximate hemoglobin concentration: 350 mg/dL) Lipemia No significant interference up to an L Index of 400 mg/dL. Rheumatoid Factor: Rheumatoid factors <76 IU/mL do not interfere. (Highest concentration tested) No high-dose hook effect was found up to ceruloplasmin concentrations of 500 mg/dL. In very rare cases, gammopathy, in particular type IgM (Waldenstrom's macroglobulinemia), may cause unreliable results.	Criterion: Same Icterus: Same Hemolysis: Same Lipemia (Intralipid): No significant interference up to an L index of 200. There is poor correlation between the L index (corresponds to turbidity) and triglyceride concentration. RF: Rheumatoid factors up to 100 IU/mL do not interfere. High-dose hook effect: Same Same
Expected Values	Male: 15-30 mg/dL Female: 16-45 mg/dL	20.0 – 60.0 mg/dL
Method Comparison	A comparison of the Roche Tina-quant Ceruloplasmin assay (x) with the Roche Ceruloplasmin assay on cobas c510 (y) gave the following correlation (mg/dL) : Passing Bablock: $y = 1.02x + .302$, $\tau = 0.934$ Linear Regression: $y = 0.980x - 0.411$, $r = 0.997$ n = 82 Samples concentrations were between 13.2 and 132.1 mg/dL	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Roche Diagnostics
c/o Ms. Kathie Goodwin, MBA, MT (ASCP)BB, RAC
Regulatory Affairs Consultant
9115 Hague Road, PO Box 50416
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MAR 18 2010

Re: k091741
Trade/Device Name: Tina-Quant Ceruloplasmin
Regulation Number: 21 CFR § 866.5210
Regulation Name: Ceruloplasmin Immunological Test System
Regulatory Class: Class II
Product Code: CHN
Dated: March 2, 2010
Received: March 10, 2010

Dear Ms. Goodwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k091741

Device Name: **Roche/Hitachi Tina-Quant Ceruloplasmin**

Indication For Use:

In vitro test for the quantitative determination of ceruloplasmin in human serum and plasma on Roche automated clinical chemistry analyzers.

Prescription Use XXXX (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k091741